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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/209,799	12/11/98	HERMELING	R X-10242

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HM12/0915

EXAMINER

MOEZIE, F

ART UNIT	PAPER NUMBER
1653	11

DATE MAILED: 09/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/209,799

Applicant(s)

Hermeling

Examiner

F. T. Moezie

Group Art Unit

1653



☒ Responsive to communication(s) filed on Jul 11, 1900

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 26-46 is/are pending in the application.

Of the above, claim(s) 26-32, 44, and 45 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 33-43 and 46 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 26-46 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

STATUS OF CLAIMS

Claims 33-43 and 46, drawn to flat rod-shaped or plate-like crystals of Val-8 GLP-1 (7-37) OH and compositions made therefrom, are examined on their merits in this Office action. See below for explanation.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is a lack of description for the crystals of Val-8 GLP-1 (7-37) OH, obtained from a solution comprising a monosaccharide or disaccharide in the crystallization solution. The mere citation of a list of every possible moiety does not constitute a written description for the moieties. See, e.g., *Fujikawa v. Wattanasin*, 39 USPQ 1895, 1905 (Fed. Cir. 1996).

Claims 33-43 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using ethanol or propanol as the crystallization solution,

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does not reasonably provide enablement for a mono or a disaccharide in the crystallization solution as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the crystals of the invention commensurate in scope with these claims. Crystal formation in the field of protein chemistry is highly dependent on the characteristics (polarity, ionic strength, pH and etc.) of the solution from which the protein is crystallized. The use of mon- or disaccharides in the crystallization media would alter the characteristics of the crystallization media and also effects the conformation of the protein being crystallized. Hence, each solution would have to be examined separately for its efficacy in crystal formation.

Claims 33-43 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite and vague regarding the crystallization solution. It is apparent that the aqueous solution has been used ⁱⁿ the instant methods. However, the ^{claims} fail to specify the "aqueous" nature of the solvent. Moreover, the term "v/v" or "^{wt}w/v" is indefinite as to what the respective amounts are compared with.

Claim 40 is an indefinite and improper composition claim, being drawn to a composition comprising "individual flat-rod shape" OR "plate-like crystals".

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Claims 40 and 43 are indefinite and substantial duplicates of one another. A new preamble for a claim does not distinguish the substance of the new claim over the old claim.

In claim 46 the terminology "remain suspended in liquid medium for a longer period of time than crystalline clusters or amorphous crystals" render the claim indefinite as to which liquid medium has the claimed capability and for how much longer do the crystals stay suspended and what is the source of comparison.

RESPONSE TO APPLICANT

Restriction Requirement set forth earlier in paper no. 4, mailed 10/15/99 has been applied to the newly added claims 28-45. Earlier applicant elected, without traverse, Group II invention, claims drawn to crystals of GLP-1 (claims 7-22). Newly added claims 33-43 and 46, drawn to the crystals of Val-8 GLP-1(7-37) OH, corresponding to the earlier elected invention are examined in this Office action. The restriction requirement is made FINAL.

Claims 26-32 and 44-45, drawn to a process for preparing crystals of GLP-1 (7-37) OH, and methods of use are withdrawn from consideration by the examiner as being drawn to the non-elected subject matter. Cancellation of the non-elected claims is advised.

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The earlier rejections of the claims (now canceled) under 35 USC 112, first and second paragraphs of 35 USC 112 are moot in view of the cancellation of these claims. However, the new claims remain rejected under the same statutes for the reasons cited above.

The rejections of the earlier claims under 35 USC 102 (b) and 35 USC 103(a) over various references are moot in view of the cancellation of the claims.

The earlier rejection of the claims under the obviousness double patenting is moot in view of the cancellation of the claims.

DECLARATION UNDER 37 CFR 1.132

The declaration filed under 37 CFR 1.132 has been considered and found persuasive. Claims rewritten commensurate in scope with the scope of the Declaration will be considered for allowance.

CONCLUSION:

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508.

F. T. Moezie
F. T. MOEZIE, Ph.D.
PRIMARY EXAMINER
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